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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,264	03/23/2001	Andrey A. Boukharov	38-21(51237)G	8785

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,264

Applicant(s)

BOUKHAROV ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-11 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-5 and 8-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5, 8-11, and 38-39 in the reply filed on 4/7/05 is acknowledged. The traversal is on the ground(s) that there is no serious burden to the examiner of all claims are examined together. This is not found persuasive because a search for cells, animals, or other transgenic organisms requires a search of the prior art not required for a nucleic acid sequence, per se. For example, results from a search of an EST database, or the NCBI database for a nucleic acid sequence does not necessarily produce results with regard to transgenic organisms. In addition, a search for any single Group requires a search of nonpatent literature and foreign patent databases as well as US patents and publications. For these reasons, the examiner maintains that it would be burdensome to search for both nucleic acid sequences and transgenic organisms.

In the event that the transgenic organisms of the new claims are considered a "subcombination" of the "combination" recited in the original claims, applicant's attention is directed to MPEP 806.05, which states that:

"Where a combination as claimed does not set forth the details of the subcombination as separately claimed and the subcombination has separate utility, the inventions are distinct and restriction is proper if reasons exist for insisting upon the restriction; i.e., separate classification, status, or field of search.

This situation can be diagrammed as combination ABbr ("br" is an abbreviation for "broad"), and subcombination Bsp ("sp" is an abbreviation for "specific"). Bbr indicates that in the combination the subcombination is broadly recited and that the specific

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characteristics set forth in the subcombination claim Bsp are not set forth in the combination claim.

Since claims to both the subcombination and combination are presented and assumed to be patentable, the omission of details of the claimed subcombination Bsp in the combination claim ABbr is evidence that the patentability of the combination does not rely on the details of the specific subcombination.

In the instant case, transgenic organisms are classified separately from nucleic acids, as set forth in the restriction requirement. In addition, as transgenic organisms are not "useful" for the same purposes as are nucleic acids (e.g. one skilled in the art does not use a transgenic plant as a promoter to express another sequence), the combination and "subcombination" would be expected to have different utilities.

For all of the reasons set forth above, the requirement is still deemed proper and is therefore made FINAL.

Claim 40 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Claims 41-45 are also directed to transgenic organisms; i.e. the same subject matter as Group II, and are therefore also withdrawn. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/7/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by WING et al. (NCBI Acc. No. AZ134591), as supported by MEINKOTH et al. (Analyt. Biochem. (1984) vol. 138, pp. 267-284). This rejection is necessitated by the amendment filed 4/7/05.

WING teaches a nucleic acid sequence which is only 20.8% identical, but 94.7% similar over its length to instant SEQ ID NO: 1. The instant specification teaches on page 12 that low stringency conditions range from about 0.15 M to about 0.9 M sodium chloride and temperatures ranging from about 20°C to about 55°C. Using the equation set forth on page 269 of MEINKOTH wherein %formamide+0, (%G+C)=33, and subtracting 18 for the mismatch (p. 269 of MEINKOTH), the T_m for 0.15M salt = 61.9°C and the T_m for 0.9M salt = 74.8°C. Thus, the nucleic acid of WING would be expected to hybridize to instant SEQ ID NO: 1 under the range of salt and temperature which are "low stringency conditions", and claim 1 is anticipated.

Allowable Subject Matter

Claims 2-5 and 8-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 38-39 are allowable.

The following is a statement of reasons for the indication of allowable subject matter: the prior art neither teaches nor fairly suggests a sequence which exhibits at least 90% identity to SEQ ID NO: 1, and SEQ ID NO: 1 has utility as a promoter, as previously set forth.

Conclusion

Claim 1 is rejected; claims 2-5 and 8-11 are objected to. Claims 40-45 are withdrawn. Claims 38-39 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
6/27/05